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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/840,730

04/23/2001

Michael R. Hufford

IVQ-003

4534

959

7590

09/22/2006

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

SMITH, TRACI L

ART UNIT

PAPER NUMBER

3629

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/840,730

Applicant(s)

HUFFORD ET AL.

Examiner

Traci L. Smith

Art Unit

3629

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 27 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
JOHN G. WEISS  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600

### **DETAILED ACTION**

This action is in response to papers filed on July 27, 2006.

No claims have been amended.

Claims 1-51 are pending.

Claims 1-51 are rejected.

### ***Response to Arguments***

1. Applicant's arguments and request of for reconsideration filed July 27, 2006 have been fully considered but they are not persuasive.
2. As to applicants arguments regarding the fact that the prior art of record Kardis fails to teach an "instrumented" paper diary, as claimed in claims 1, 22 and 51, that there is not actually paper with Kardis. Applicant is requested to review C. 9 8 I. 1-5 Fig. 38 in which Kardis discloses "a sheet or a pad (Fig. 11) of paper which is superimposed or engagingly position on the working surface of a recording unit." Therefore, Kardis anticipated the "instrumented paper diary". Furthermore, as to applicants argument that Kardis does not "generate a record of use of the paper diary". Applicant claims merely state generating a record containing information "regarding" the use of the diary. The applicant is not claiming that a record is generated when or by the use of the diary. The limitation of "information regarding the use of the paper dairy", is a broad limitation.
3. As to applicants arguments regarding claims 2-21 and 23-32 are the same arguments as given in the independent claims the examiner notes for the same reasons the arguments are not persuasive.

4. As to applicants arguments with regard to Claim 33 and Straka failing to recited a "paper diary". It is noted that that the paper diary as claimed is merely non-functional descriptive data. The steps of the compliance monitoring would be performed regardless of the type of apparatus being used in the monitoring, ie, the vial used in Straka monitors and records data according to the opening and closing of the vial. The recording of an opening and closing of the diary can be considered "related to the entry" and is monitored in the same steps as the vial. The diary is never further used in the claims as noted previously, the data is "related" to the entry in a paper diary, not generated from or the actual entry of the diary. As to applicants arguments that Straka cannot detect proactive or retroactive data entry, the examiner notes this is intended us, how the applicant intends to use the monitoring system and does not patentably distinguish itself from the prior art.

5. Claims 38-39 stand rejected for the same reasons as stated above for claim 33.

6. As to claims 34-37 and 40-41 applicant argues against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

7. As to applicants arguments regarding claims 42 and 47 Hyland's teachings applicants arguments are not persuasive. Applicant argues that Hyland does not generate a record "concerning" the use of a paper diary. In response to applicant's arguments against the references individually, one cannot show nonobviousness by

attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). However the examiner notes when given it's broadest reasonable interpretation claim 42 merely reads that there is an electronic record containing information about using a paper diary not a record that is "generated" by the use of the paper diary. Hyland disclosed using an electronic record and a paper record for comparison of information entered by the patient.(Pg. 1 C. 2 last paragraph). Lastly, as noted earlier Kardis teaches an "instrumented paper diary"( C. 9 8 l. 1-5 Fig. 38)

8. Claims 43-46 stand rejected for the same reasons as stated above for claim 42.

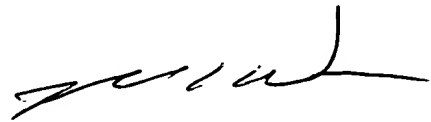
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traci L. Smith whose telephone number is 571-272-6809. The examiner can normally be reached on Monday-Thursday 6:00 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 571-272-6812. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS



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